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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,633	11/14/2006	Shite Sebastian	3265.1010-004	4672

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,633	SEBASTIAN ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending in the application.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a) (1) and (a) (2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 because where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of 37 C.F.R. § 1.821, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. In the instant case, the peptides disclosed in the claims lack the requisite sequence identifier preceded by "SEQ ID NO:' Applicant is required in response to this office action to comply with the sequence rules set forth in 37 C.F.R. § 1.821-1.825.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to a method for detecting the presence or absence of a bacterium, comprising the steps of: a) contacting a sample with a detectably labeled synthetic serpin reactive site loop domain peptide substrate under conditions that result in modification of said substrate by an enzyme produced by a bacterium; and b) detecting a modification or an absence of the modification of the substrate, the modification of the substrate indicating the presence of the

bacterium in the sample and absence of the modification of the substrate indicating absence of the bacterium in the sample..

Group II, claim(s) 13-21, drawn to A biosensor for detecting the presence or absence of a bacterium in a sample, the biosensor comprising: a) a solid support and b) a detectably labeled synthetic serpin reactive site loop (RSL) domain peptide substrate, said substrate attached to said solid support.

Group III, claim(s) 22, drawn to an isolated peptide comprising a detectable label and an amino acid sequence selected from the group consisting of EAAGAMFLEAIPK, EGAMFLEAIPMSIPK, KGTEAAGAMFLEAIPMSIPPEVK, GAMFLEAIPMSIPPE, and CGAMFLEAIPMSIPAAAHHHHH.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature linking Groups I-III is a serpin reactive site loop domain peptide. This technical feature is anticipated by Travis et al (WO 00/63394, October 26, 2000). Travis et al teach a serpin reactive site loop domain peptide (see SEQ ID NO: 4, p. 6/6 of the drawings section of Travis et al) which is 100 % identical to a serpin reactive site loop domain peptide (see SEQ ID NO: 4 in fig. 1 and claim 22 of the instant application). Thus, the technical feature linking the inventions of Groups I-III is not special within the meaning of PCT Rule 13.2.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I

1. Species of bacterium - *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Pseudomonas aeruginosa, Enterococcus faecalis, Serratia marcescens, Proteus mirabilis, Enterobacter clocae, Acetinobacter anitratus, Klebsiella pneumonia, and Escherichia coli.*
2. Species of labels - spin labels, antigen tags, epitope tags, haptens, enzyme labels, prosthetic groups, fluorescent materials, pH-sensitive materials, chemiluminescent materials, colorimetric components, bioluminescent materials, and radioactive materials.
3. Species of peptides- EAAGAMFLEAIPK, EGAMFLEAIPMSIPK, KGTEAAGAMFLEAIPMSIPPEVK, GAMFLEAIPMSIPPE, and CGAMFLEAIPMSIPAAAHHHHH.
4. Species of support - wound dressing, a container for holding body fluids/ urine collection bag, a disk, a scope, a filter, a lens, a foam, a cloth, a paper, a suture, a dipstick, a swab, a container for holding body fluids/ a blood collection bag, a container for holding body fluids/a plasma collection bag, a container for holding body fluids/a test tube, a catheter, and a well of a microplate.

Group II

1. Species of bacterium - *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Pseudomonas aeruginosa, Enterococcus faecalis, Serratia marcescens, Proteus mirabilis, Enterobacter clocae, Acetinobacter anitratus, Klebsiella pneumonia, and Escherichia coli.*
2. Species of labels - spin labels, antigen tags, epitope tags, haptens, enzyme labels, prosthetic groups, fluorescent materials, pH-sensitive materials, chemiluminescent materials, colorimetric components, bioluminescent materials, and radioactive materials.

3. Species of peptides- EAAGAMFLEAIPK, EGAMFLEAIPMSIPK, KGTEAAGAMFLEAIPMSIPPEVK, GAMFLEAIPMSIPPE, and CGAMFLEAIPMSIPAAAHHHHH.
4. Species of support - wound dressing, a container for holding body fluids/ urine collection bag, a disk, a scope, a filter, a lens, a foam, a cloth, a paper, a suture, a dipstick, a swab, a container for holding body fluids/ a blood collection bag, a container for holding body fluids/a plasma collection bag, a container for holding body fluids/a test tube, a catheter, and a well of a microplate.

Group III

1. Species of peptides- EAAGAMFLEAIPK, EGAMFLEAIPMSIPK, KGTEAAGAMFLEAIPMSIPPEVK, GAMFLEAIPMSIPPE, and CGAMFLEAIPMSIPAAAHHHHH.

The claims are deemed to correspond to the species listed above in the following manner:
Claims 2, 5, 6,9,14,17,18,19 and 22,
The following claim(s) are generic: 1, 3, 4,7,8,11,12,13,16,20 and 21.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:
The species of bacterium lack a common structure and pathogenic function; the species of labels lack a common structure; the species of support lack a common structure and function; and the peptides lack a common structure, in addition Travis et al teach the peptide with the amino acid GAMFLEAIPMSIPPE (see p. 6/6 of Travis et al, WO 00/63394, October 26, 2000).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to

OLUWATOSIN OGUNBIYI whose telephone number is (571)272-9939. The examiner can normally be reached on M-F 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shannon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Oluwatosin Ogunbiyi
Examiner, Art Unit 1645

/Robert A. Zeman/
for Oluwatosin Ogunbiyi, Examiner of Art Unit 1645